DRAFT

A Guide for Determining the Usefulness

of

Consumer Medicine Information (CMI)

Prepared by the

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Attachment A

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Purpose

This Guide for Determining the Usefulness of Consumer Medicine Information (CMI) is intended for database publishers who prepare monographs of written prescription drug information for consumers, for pharmacy systems vendors who incorporate this information into software delivered to pharmacies, for pharmacies that dispense written information with prescriptions to patients, and for regulators (and their contractors) who evaluate the usefulness of written information about prescription drugs dispensed by pharmacies to patients. The Guide provides detailed guidance on how to interpret and operationalize the Keystone Committee's *Guidelines for Useful [Written] Prescription Medicine Information*, i.e., Chapter 3 and Appendix G of the Keystone Action Plan, for the purposes of developing and evaluating written CMIs for "usefulness."

The goal of this document is to provide guidance to developers and evaluators of CMIs to achieve compliance with the Keystone Action Plan for the provision of useful written prescription drug information. There may be more effective ways to provide useful written information to consumers than was recommended in the Keystone Action Plan. It is not our intent to stifle more innovative ways to inform and educate consumer about their prescription medications.

This Guide was developed by the Criteria Committee of the National Council on Medication Information and Education's (NCPIE) CMI Initiative in collaboration with the US Food and Drug Administration.

Criteria for CMIs

Per the Keystone Action Plan:

CMIs will be 1) scientifically accurate; 2) unbiased in content and tone; 3) sufficiently specific and comprehensive; 4) presented in an understandable and legible format that is readily comprehensible to consumers; 5) timely and up-to-date; and 6) useful.

General Guidance

- CMIs will be evaluated for content and format in determining usefulness.
- CMIs will be evaluated using ONLY the FDA-approved professional labeling.
- CMIs for generalized distribution may contain RISK information not in FDA-approved labeling if supported by the weight of the available scientific evidence.

- CMIs for generalized distribution should NOT contain off-label use information, but customizable CMIs may contain this information.

Acceptable Layouts

The Keystone Action Plan described four possible layouts for the provision of useful written consumer medicine information. Layout 1 is described on pages 24-25 of Chapter 3 of the Action Plan. Layouts 2, 3, and 4 are taken from the examples provided in Appendix G of the Action Plan. Developers and evaluators of written CMIs should consider these layouts acceptable for providing useful written information. The headings listed in these layouts are intended as concepts. Alternative layouts may be acceptable for useful CMIs.

Layout 1

- Personalized information (optional)
- Established name and brand name
- Black Box Warning (if applicable)
- "This medicine is used for..."
- "Do not take this medicine if you are..."
- "How to take this medicine..."
- "Side effects include..."
- General Information

Layout 2

- Personalized information (optional)
- Established name and brand name
- Black Box Warning (if applicable)
- "Why is XXXX prescribed?"
- "Before taking your medicine..."
- "While you are taking your medicine..."
- General Information

Layout 3

- Personalized information (optional)
- Established name and brand name
- Black Box Warning (if applicable)
- "What is XXXX?"
- "Who should not take XXXX?"
- "How should I take XXXX?"
- "What are the possible side effects of XXXX?"

- "How should I store XXXX?"
- General Information

Layout 4

- Personalized information (optional)
- Established name and brand name
- Black Box Warning (if applicable)
- Summary (optional)
- Uses
- General Cautions
- Proper Use
- Possible Side Effects
- Storage
- General Information

Components of Useful Information to be Included

Drug Name

- Established (generic) name should be included.
- Phonetic spelling of established (generic) name should be included.
- Brand name should be included if applicable, e.g., if a brand name drug was dispensed.

Black Box Warning (if applicable)
(Note: See "Precautions and Warnings" section below for other warnings)

- Drugs that have a black box warning in FDA-approved professional labeling that is relevant to the consumer should contain a scientifically accurate warning in the CMI. This black box warning should be displayed prominently in words that the consumer will understand. Two examples of black box warnings that are consumer oriented are:
    - Carbamazepine can have side effects in your blood, and in rare cases this can cause death. Your doctor should do blood tests to check for these side effects.
    - Rarely, lamotrigine can cause life-threatening skin rash. This is more common in children than adults. If you get a skin rash, stop taking lamotrigine and contact your doctor immediately.

Indication(s) for Use

- This information should be included under the following sections for the various layouts:
    - Layout 1 – "This medicine is used for…"
    - Layout 2 – "Why is XXXX prescribed?"
    - Layout 3 – "What is XXXX?"
    - Layout 4 – Uses
- From the Indications section of the FDA-approved professional labeling, the CMI should list the FDA-approved indications for the drug, presented in words that the consumer will understand (e.g., high blood pressure for hypertension).
- When all possible uses of the drug are not included in this section, a general statement should be included that the drug may be used for other indications. For example:
    - "Medicines are sometimes prescribed for uses other than those listed in this leaflet. If you have any questions, please call your doctor."
- It is optional to include information about the therapeutic or pharmacologic class, or about the mechanism of action of the drug.

Contraindications

- This information usually will be included under the following sections for the various layouts:
    - Layout 1 – "Do not take this medication if you are…"
    - Layout 2 – "Before taking your medicine…"
    - Layout 3 – "Who should not take XXXX?"
    - Layout 4 – General Cautions
- From the Contraindications section of the FDA-approved professional labeling, include information on circumstances (e.g., pre-existing disease, drug interactions, pregnancy, allergy, etc.) under which the drug should not be used for its labeled indication(s); this information should be presented in words that the consumer will understand (e.g., over active thyroid for hyperthyroidism).
- Based on the FDA-approved labeling, include directions to the consumer on what to do (e.g., "contact your doctor") if any of the contraindications apply; a general statement, such as "Talk to your doctor before taking this medication if any of these apply to you," may be sufficient.

Proper Use

- This information usually will be included under the following sections for the various layouts:
    - Layout 1 – "How to take this medicine if you are…"
    - Layout 2 – "While you are taking your medicine…"
    - Layout 3 – "How should I take XXXX?"
    - Layout 4 – Proper Use

- Include directions about how to use the drug and other advice to optimize the effectiveness of the drug; information will usually come from the Dosage and Administration section of FDA-approved professional labeling and from Keystone Chapter 3.

- Per Keystone Chapter 3, this section of the CMI should contain statements on the following:
    - The importance of adherence to the dosing instructions prescribed by your doctor.
    - What to do in case of a missed dose.
    - Any specific instructions on how to administer the drug (e.g., route of administration, with or without food and/or water, at specific times per day, et cetera).
    - If determined to be important, information on overdosage, including signs/symptoms (consumer-friendly language), and directions on what the patient should do (e.g., call an emergency number or poison control center). (Note: This information usually will come from the Overdosage section of FDA-approved professional labeling.)
    - If not in another section of the CMI, directions on proper storage of the drug.

Precautions and Warnings
(Note: For purposes of compliance with the Keystone Action Plan, this section may include information from precautions, warnings, and [possibly] contraindications sections of FDA-approved professional labeling.

- This information usually, but not always, will be included under the following sections for the various layouts:
    - Layout 1 – "Do not take this medicine if you are…" OR "How to take this medicine…"
    - Layout 2 – "Before taking your medicine…" OR "While you are taking your medicine…"
    - Layout 3 – "Who should not take XXXX?" OR ""How should I take XXXX?"
    - Layout 4 – General Cautions

- In Layouts 1, 2, and 3, the appropriate placement of a precaution should depend on whether it is applicable before the drug is taken or during the course of therapy. Occasionally, a precaution more appropriately may be placed in another section of the CMI, e.g., Proper Use, to enhance the usefulness of the information.

- From the Precautions and Warnings sections of the FDA-approved professional labeling (and using Keystone Chapter 3 as a guide), include information on circumstances under which use of the drug for the labeled indication(s) could result in

serious adverse consequences for the patient, or in circumstances where the drug has the potential to cause a particularly serious adverse reaction; this information should be presented in words that the consumer will understand (e.g., low blood sugar for hypoglycemia).

- Keystone Chapter 3 encourages statements of precautions in "serious situations." Preparers of CMIs should use their judgment on what to include.

- Keystone Chapter 3 recommends that this information be presented as statement(s) of precautions the consumer should take to ensure proper use of the medicine. Examples (NOT all inclusive) are as follows:
    - Because XXXX may cause drowsiness, avoid driving a motor vehicle.
    - Because XXXX may cause your skin to burn, avoid sunbathing or unnecessary exposure to sunlight.
    - Call your doctor immediately if you experience ZZZZ. [Where ZZZZ are symptoms suggesting a serious adverse reaction.]
    - Talk to your doctor if you are taking the following medications, YYYY or ZZZZ. [Because XXXX may interact with YYYY and ZZZZ.]
    - Do not eat the following foods, AAAA or BBBB, while taking XXXX. [Because XXXX may interact with AAAA and BBBB.]
    - Do not consume alcohol while taking XXXX. [Because XXXX interacts with alcohol.]
    - Tell your doctor if you have AAAA. [Where AAAA is a pre-existing disease.]
    - If you are pregnant, talk to your doctor before taking XXXX.
    - If you are breast feeding, talk to your doctor before taking XXXX.
    - For pregnancy and breast feeding, Keystone also will allow a general statement if the risks are unknown, such as "When taken during pregnancy, labor, and breast-feeding, the effects of XXXX on the development of the exposed offspring are unknown."
    - For children under the age of HH, XXXX has been associated with DDDD. Talk to your doctor if there are any questions.
    - For other identifiable patient populations, (e.g., geriatric patients) additional precautions that apply to the safe and effective use of the medicine in that population.

  - Do not stop taking XXXX suddenly as it may cause EEEE. Gradual dose reduction may be needed. Talk to your doctor.
  - Talk to your doctor if you have any of the following diseases or conditions, FFFF or GGGG. [Because XXXX must be used cautiously in these patients, although it is not contraindicated.]

- For some drugs, a general statement, such as "Talk to your doctor before taking this medication if any of these apply to you," may be sufficient.

Possible Adverse Reactions

- This information usually will be included under the following sections for the various layouts:
  - Layout 1 – "Side effects include..."
  - Layout 2 – "While you are taking your medicine..."
  - Layout 3 – "What are the possible side effects of XXXX?"
  - Layout 4 – Possible Side Effects

- From the Adverse Reactions section of the FDA-approved professional labeling, the CMI should contain the symptoms of serious or frequent adverse reactions and, when appropriate, inform the consumer what to do; this information should be presented in words that the consumer will understand (e.g., muscle aches for myalgias).

- Keystone Chapter 3 encourages the inclusion of adverse reactions that are serious and/or occur frequently. Preparers of CMIs should use their judgment on what to include.

- Keystone Chapter 3 provides some latitude on how information about adverse reactions is to be organized and explained. The information can be organized by organ system, severity, or frequency, or a combination of these approaches, or using other appropriate means. The sample CMIs in Appendix G provide examples.

- Information about an adverse reaction should be presented as "symptoms," using words that the consumer will understand. For example:
  - For orthostatic hypotension, symptoms such as "dizziness or lightheadedness, especially when getting up from a sitting or lying position."

- When an adverse reaction requires the attention of the prescriber, a statement should be included. For example:
  - "Call your doctor if the following side effects occur."

Tolerance/Physical Dependence and Withdrawal/Drug Abuse

- For drugs that are subject to abuse and which have a section in FDA-approved professional labeling on Drug Abuse and Dependence (e.g., opioids, barbiturates, benzodiazepines, and amphetamines), information on tolerance, physical dependence, and withdrawal, and drug abuse should be included in the CMI.

- This information usually will be included under the following sections for the various layouts:
    - Layout 1 – "How to take this medicine…"
    - Layout 2 – "While you are taking your medicine…"
    - Layout 3 – "How should I take XXXX?"
    - Layout 4 – General Cautions

- From the Drug Abuse and Dependence section of the FDA-approved labeling, or when available from a section that provides Information for Patients specific to drug abuse and dependence, information should be included in the CMI to get across the concepts of tolerance, physical dependence, withdrawal, and drug abuse, when any of these may be applicable to the drug. As appropriate, include directions to the consumer on what to do. This information should be presented in words that the consumer will understand.

Proper Storage

- For Layouts 1 and 2, include instructions on proper storage of the drug in the sections entitled, "How to take this medicine…" and "While you are taking your medicine…," respectively.

- For Layouts 3 and 4, include instructions on proper storage of the drug in the sections entitled, "How should I store XXXX?" and Storage, respectively.

General Information

- The Keystone Action Plan recommends that CMIs have some "General Information" statements. Each of the Layouts 1-4 has a section at the end entitled, "General Information," in which the following information should be included:

    - A statement encouraging discussion with a health care professional about the prescription medicine.
    - A statement that the medicine should only be used by the patient for whom it is prescribed and is not to be given to other persons. (Note: While not required by Keystone, a statement to "Keep all medications out of reach of children." may be included.)

- The name of the publisher of the information.
- The date of publication or most recent revision or review for adequacy and accuracy of content.

- In addition, the Keystone Action Plan also requires a "disclaimer" statement that contains the following concepts:
  - The materials are summaries and do not contain all possible information about the medicine.
  - The health care professional who has prescribed the medicine has more information.
  - The health care professional's information addresses both the medicine and the patient's specific health needs.
  - The health care professional can provide and answer questions about the information in the professional labeling.

Optional Components of Useful Information

- Personalized Information (optional): Personalized information may be included. If personalized information is included, then the CMI is considered customized and is not acceptable for generalized distribution.

- Per Chapter 3 of the Keystone Action Plan, a Summary section (containing the medicine's approved indications, critical aspects of proper use, significant warnings, precautions, contraindications, serious adverse reactions, and potential safety hazards) is optional. Layout 4, and the sample leaflet in Appendix G that uses this layout, provides an example of a Summary section.

- Per Chapter 3 of the Keystone Action Plan, providing a toll-free number to a service which provides information for consumers with impaired vision, marginal or no literacy, or whose first language is not English is optional.

Information is Scientifically Accurate, Unbiased in Content and Tone, and Timely and Up-to-date

To meet these three criteria, as mandated by the Keystone Action Plan (Chapter 3) for CMIs to be considered useful, the requirements listed in the study by Svarstad et al, "Evaluation of Written Prescription Information Provided in Community Pharmacies, 2001," should be satisfied. These are:

- The information presented in the CMI should be neutral [unbiased] in tone and content. Based on Keystone Chapter 3, this means:
  - The information represents fair balance between descriptions of the benefits and descriptions of the risks of the drug.

- The information is explanatory, neutral, without comparative adjectives, without untruthful claims about the benefit of the product, and without hyperbole.
- The information is not associated with any promotional or other information provided to the patient.
- The presentation and content of the information should meet the accepted standards of scientific literature.

(Note: See the sample leaflets in Appendix G for examples of neutral tone and content.)

- No information about indications or uses that are not in the FDA-approved labeling, i.e., off-label uses, can be included in generalized CMIs. (Note: Customizable CMIs may include off-label use information).

- The CMI cannot contain any promotional messages about a specific brand of drug, a manufacturer, or a distributor.

- Consistent with FDA-approved professional labeling, the CMI should not contain inaccurate or outdated claims about benefits or risks of a drug and should not contain other inaccurate or outdated information.

- Developers of CMI information should rely on the most recent FDA-approved professional labeling and make changes to CMIs, consistent with changes to professional labeling, in a timely manner. Pharmacy system vendors and pharmacies should incorporate the most current CMIs into their systems in a timely manner.

Information is Readily Comprehensible and Legible

To meet this criterion, as mandated by the Keystone Action Plan (Chapter 3) for CMIs to be considered useful, the information provided in Chapter 3 and Appendix G of the Keystone Action Plan, as well as the requirements listed in the study by Svarstad et al, "Evaluation of Written Prescription Information Provided in Community Pharmacies, 2001," were considered. The following recommendations are made:

- The information should be well organized and easy to find. Specific suggestion:
  - A standardized format, e.g., Layouts 1-4 described above, should be adopted by database publishers so that information is presented in the same order for all drugs.

- Headings should be differentiated from text. Specific suggestions:
  - Use "sans serif" font, bold-face type, and larger point type for headings; use "serif" font, primarily light-face type (see below for exceptions), and smaller (but at least 10-point) type for text.
  - Differentiating headings from text in a similar manner to any of the sample leaflets in Appendix G will satisfy this requirement.

- Short paragraphs and bullets should be used where possible to enhance readability (see the sample leaflets in Appendix G).

- The use of bold-face type or boxed text is encouraged to prominently display particularly important information.

- Ornate typefaces and italics, which are hard to read, should not be used. Suggestion:
    - As discussed above, use "sans serif" font for headings and "serif" font for text (per Appendix G).

- Upper and lower case lettering should be used.

- CMIs should be printed in no smaller than 10-point type.

- There should be adequate space between letters, lines, and paragraphs to enhance readability. Suggestions (per Appendix G):
    - Space between letters – no more than -3 kerning.
    - Space between lines – use 12-point leading with 10-point type
    - Space between paragraphs or between headings and text - Keystone does not specify other than that adequate space between paragraphs and space above and below headings can facilitate reading. Adhering to what was done in sample leaflets in Appendix G should satisfy this requirement.
    - Line length – optimal line length is approximately 40 letters long (in 10-point or 12-point type) per Appendix G.

- There should be good contrast between the ink and paper colors because good contrast will facilitate reading. Suggestions:
    - Black, dark blue or brown ink on pale yellow or white paper provides the best contrast and is recommended in Appendix G.
    - The following combinations should be avoided because they provide insufficient contrast – brown on gold, blue on green, and red on pink.
    - Information should be printed on uncoated paper, as recommended in Appendix G.

- CMIs preferably should be written at the sixth- through eighth-grade reading levels.

End